



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

94380d

San Francisco District
1431 Harbor Bay Parkway
Alameda, CA 94502-7070
Telephone: 510/337-6700

VIA FEDERAL EXPRESS

Our Reference: CFN/FEI 2953897/3001604659

October 30, 2003

Sean C. Martin, President
Pacific Ocean Producers, Inc.
965-B North Nimitz Highway
Honolulu, Hawaii 96817

WARNING LETTER

Dear Mr. Martin:


On August 25 and 27, 2003, we inspected your seafood processing facility located at 965-B North Nimitz Highway, Honolulu, Hawaii, and found that you have serious deviations from the seafood Hazard Analysis Critical Control Point (HACCP) regulation in Title 21, Code of Federal Regulations, Part 123 (21 CFR 123). These deviations cause your tuna to be adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act), in that the fish have been prepared, packed, and held under insanitary conditions whereby it may be rendered injurious to health. You may find the Act and the seafood HACCP regulation through links in FDA's home page at www.fda.gov. The attached handout explains how you can obtain a copy of the Fish & Fisheries Products Hazards & Controls Guidance, 3rd edition, June 2001. We listed the deviations on a Form FDA 483 and discussed them with you at the conclusion of the inspection.

Your HACCP deviations are as follows:

1. You must have a HACCP plan that, at a minimum, lists the critical limits that must be met at each critical control point, to comply with 21 CFR 123.6(c)(3). A critical limit is defined in 21 CFR Part 123.3 (c) as "the maximum or minimum value to which a physical, biological, or chemical parameter must be controlled at a critical

control point to prevent, eliminate, or reduce to an acceptable level the occurrence of the identified food safety hazard.” However, your plan for Frozen Albacore Tuna lists a critical limit of “Product received solidly frozen; no sensory evidence of decomposition” at the Receiving critical control point which is not adequate to control the hazard of histamine formation.

You must ensure that the fish you receive are safely handled prior to your receipt, both during harvest and while on-board the fishing vessel. FDA recommends that you ensure safe handling prior to receipt by 1.) organoleptic examination for decomposition, and 2.) either histamine testing of a representative number of fish per lot or by requiring harvest vessel records from the vessels. If you choose to use harvest vessel records, your HACCP plan should list the critical limits concerning the handling of the fish aboard ship (i.e., method of capture, date and time of landing, estimated time of death, air/water temperatures, method of cooling, date/time cooling began, cooling rate, storage temperature, date and time of off-loading). The Vessel Standard Operating Procedure certification record is not a sufficient substitute.

Scientific research indicates that if more than 2.5% of a lot of fish is decomposed, the likelihood of temperature abuse and histamine formation throughout the lot is increased. We suggest that you include a critical limit of 2.5% decomposition for organoleptic examination at the Receiving CCP. In addition, you have listed that you will monitor  fish per load. FDA recommends a minimum of 118 fish or the entire lot if the lot consists of less than 118 fish, in order to achieve a representative sample for decomposition evaluation.

You may refer to Chapter 7 of the Fish & Fisheries Products Hazards and Controls Guidance for examples of adequate critical limits and monitoring procedures/frequencies for both histamine testing and harvest vessel records.

2. You must implement the record keeping system that you have listed in your HACCP plan, to comply with 21 CFR 123.6(b). However, your firm did not record the monitoring observations at the Receiving critical control point as listed in your HACCP plan for tuna.

We may take further action if you do not promptly correct these violations. For instance, we may take further action to seize your products and/or enjoin your firm from operating. In addition, we may not provide certificates to your firm for export of products to European Union (EU) countries if you do not correct these deviations.

Please respond in writing within fifteen (15) working days of receipt of this letter. Your response should outline the specific things you are doing to correct these deviations. You may wish to include in your response documentation such as copies of the revised HACCP plan, HACCP monitoring records, or other useful information that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, we expect that you will explain the reason for your delay, and state when you will correct any remaining deviations.

This letter may not list all the deviations at your facility. You are responsible for ensuring that your processing plant operates in compliance with the Act, the seafood HACCP regulation and the Current Good Manufacturing Regulation (21 CFR Part 110). You also have a responsibility to use procedures to prevent further violations of the Federal Food, Drug, and Cosmetic Act and all applicable regulations.

Your response should be directed to: Ms. Erlinda N. Figueroa, Compliance Officer, U.S. Food and Drug Administration, 1431 Harbor Bay Parkway, Alameda, CA 94502-7070. If you have any questions regarding any issue in this letter, please contact Ms. Figueroa at (510) 337-6795.

Sincerely,

Charles D. Moss, Acting DD

Per

Dennis K. Linsley
District Director
San Francisco District

Enclosures

Handout on Fish & Fisheries Products Hazards & Controls Guidance,
3rd edition, June 2001